

REMARKS

Claims 1-7, 11 and 13-14 remain in this application. Claims 8-10, 12, and 15-16 have been canceled.

In order to emphasize the patentable distinctions of applicant's invention over the prior art, claim 1 has been amended to recite a surgical sponge comprising: (i) three substantially spherical radiopaque markers; (ii) said markers being closely grouped to one another; (iii) each of said markers having an x-ray density equivalent to at least about 0.1 g/cm² of BaSO₄; and (iv) said radiopaque markers being disposed in a relationship that is substantially fixed both in spacing and in orientation. These amendments to claim 1 represent the limitations that were previously called out by previously presented claim 16, now cancelled, and are clearly supported by the original specification. In particular the amendments to claim 1 find support in the specification, as originally filed, at page at page 15, line 22 to page 16, line 1; page 16, lines 22-24; and Fig. 10.

Other amendments to the remaining claims have been effected, for the sake of clarity and consistency, in order to correspond with the amendments to independent claim 1.

Applicant's invention provides a surgical sponge comprising a plurality of radiopaque markers having a high radiographic density and a distinctive, visually recognizable shape. The markers have an x-ray density equivalent to at least about 0.1 g/cm² of BaSO₄. The markers produce an x-ray image with high contrast and a shape that is readily recognizable and differentiated from the images produced by other items and structures commonly seen in x-rays of post-operative patients. Owing to the distinctive,

high contrast image produced by the markers, the sponge is reliably and unambiguously detected. This is so even in situations where the sponge is inadvertently left in the surgical wound. Discomfort, trauma, and possibly fatal consequences that might otherwise occur are virtually eliminated. The surgical procedure is carried out with decreased likelihood of a sponge being retained inadvertently.

Claim Rejections – 35 USC § 103

The withdrawal of the rejection of applicant's claims based on U.S. Patent 6,777,623 to Ballard is noted with appreciation.

Claims 1-10, 15 and 16 were rejected under 35 USC 103(a) as being unpatentable over Reimels (US 3,736,935).

Reimels discloses a surgical sponge useful for delicate surgical procedures which is made by providing a strip of nonwoven fibers which are securely bonded against delamination, and bonding a plastic retrieval thread to the surface of the strip by heat-softening a portion of the thread to cause it to flow partially into the surface of the strip. The resulting sponge may also have a band of radiopaque material bonded to its surface by heat-softening the plastic material of the band.

Regarding claims 1-6, the Examiner has argued that Reimels teaches a surgical sponge (10) comprising a plurality of radiopaque markers (14, 15), including barium sulfate, the markers disposed in a substantially fixed

relationship (col. 2, lines 48-59, and fig. 1). The Examiner has acknowledged that Reimels does not disclose the specific density or size of the markers. However, the Examiner has argued that mere changes in size, weight or shape are not sufficient to patentably distinguish an invention over the prior art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955) (Claims directed to a lumber package “of appreciable size and weight requiring handling by a lift truck” were held unpatentable over prior art lumber packages which could be lifted by hand because limitations relating to the size of the package were not sufficient to patentably distinguish over the prior art.); *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976)(“mere scaling up of a prior art process capable of being scaled up, if such were the case, would not establish patentability in a claim to an old process so scaled.” 531 F.2d at 1053, 189 USPQ at 148.).

The Examiner has argued that, in the instant case, it is well known in the art that increased density and size of a barium marker increases its ability to be detected by an X-ray. (see, e.g., Dyer, US Pat. No. 4,639,253, col. 3, lines 4-12). Thus, the Examiner states that, at the time of the invention, it would have been obvious to one of ordinary skill in the art to maximize the size and/or density of a barium sulfate marker in a surgical sponge in order to make it more readily detectable by an X-ray.

Applicant respectfully traverses these arguments and submits that the Examiner has not made out a *prima case* of obviousness. Nevertheless, in light of the present amendments to claims 1-6, applicant submits that present claims 1-6 clearly define over Reimels. Namely, claims 1-6, as amended, call for a

surgical sponge comprising (i) three substantially spherical radiopaque markers; (ii) said markers being closely grouped to one another; (iii) each of said markers having an x-ray density equivalent to at least about 0.1 g/cm² of BaSO₄; and (iv) said radiopaque markers being disposed in a relationship that is substantially fixed both in spacing and in orientation.

Applicant respectfully submits that nowhere does Reimels and/or Ballard disclose or suggest a surgical sponge comprising three substantially spherical radiopaque markers, the markers being closely grouped to one another. Reimels in view of Ballard discloses a surgical sponge having two or more radiopaque objects. See Reimels at col. 2, lines 48-60 and fig. 1. See also Ballard at col. 5, lines 20-38. However, Reimels in view of Ballard does not disclose or suggest three substantially spherical radiopaque markers, the markers being closely grouped to one another. See Reimels at fig. 1 which clearly shows a first radiopaque band (14) being completely separate from and on the other side of the sponge from a second radiopaque band (15). By way of comparison, present claims 1-6 require the markers being closely grouped to one another, this result having the advantage of displaying an easily detectable image on an X-ray because of the grouping arrangement of the markers in close proximity to one another.

Furthermore, there is no disclosure or suggestion in Ballard for a surgical sponge with three substantially spherical radiopaque markers, the markers being closely grouped to one another, the radiopaque markers being disposed in a relationship that is substantially fixed both in spacing and in orientation. It is

submitted that applicant's surgical sponges, as called for by present claims 1-6, are more readily discoverable by a radiologist viewing an X-ray of the patient's body because of there being three substantially spherical markers, the markers being closely grouped to one another, and disposed in a relationship that is substantially fixed both in spacing and in orientation.

In view of the amendments to present claim 1, and claims 2-7 dependent thereon, it is submitted that claims 1-6 are patentable over Reimels in view of Ballard. Accordingly, reconsideration of the rejection of claims 1-6 under 35 U.S.C. § 103(a) as being unpatentable over Reimels is respectfully requested.

Regarding dependent claim 7, the Examiner states that Reimels teaches a marker (14, 15) having distinctive linear shapes, which are detectable by an X-ray.

Applicant respectfully traverses this argument. Applicant submits that the markers (14, 15) disclosed by Reimels are simply rectangular-shaped bands, having no inherently distinctive characteristic to their shape. By way of contrast, the three closely grouped substantially spherical radiopaque markers required by applicant's claims 1-7 form a shape having a distinctive characteristic. The shape is readily detectable and observed by those viewing X-ray films of a patient. The substantially spherical shape of the three closely grouped radiopaque markers allows them to be viewed from any angle and retain their image on an X-ray film. Accordingly, reconsideration of the rejection of claim 7

under 35 U.S.C. § 103(a) as being unpatentable over Reimels is respectfully requested.

Regarding dependent claims 8, 10, and 15 (these claims being canceled and the substantially spherical limitation being incorporated into independent claim 1), the Examiner states that mere changes in shape are not sufficient to patentably distinguish an invention over the prior art. See *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.). See *Ballard* (US 6,777,623) which the Examiner states teaches a substantially spherical marker (401).

Inasmuch as claims 8, 10, and 15 have been canceled, the arguments pertaining to the substantially spherical shape to the radiopaque markers will be discussed in relation to present claim 1. Applicant submits that the substantially spherical shape to the radiopaque markers is significant to the present invention, as claimed. Namely, as stated hereinabove, the substantially spherical configuration of the three closely grouped radiopaque markers allows them to be easily detected on an X-ray film taken of a patient. The substantially spherical shape is a preferred shape because a sphere has the same cross section view from all angles; therefore, no matter what the angle and/or configuration of the sponge when the patient is X-rayed, a spherical image will be easily recognized,

especially when a close group of three substantially spherical markers are contained within the surgical sponge, as required by present claims 1-7, 11 and 13-14.

Regarding dependent claim 16, the Examiner states that Reimels teaches that more than two markers may be employed (col. 2, lines 48-59). Claim 16 has been canceled and its limitations incorporated into independent claim 1. Applicant respectfully submits that Reimels does not disclose these limitations, namely, three substantially spherical markers, the markers being closely grouped to one another. See arguments presented hereinabove.

Accordingly, reconsideration of the rejection of claim 1-7 under 35 U.S.C. § 103(a) as being unpatentable over Reimels is respectfully requested.

Claim 11 was rejected under 35 USC § 103(a) as being unpatentable over Reimels as applied to claims 1-7 above, and further in view of Ishikawa et al. (US 6,366,206).

Ishikawa et al. disclose a method and apparatus for attaching one or more transponders to medical and non-medical products to tag respective ones of the products with identifying data contained in a memory of the transponders. The one or more transponders each include a memory containing the corresponding identifying data which is emitted by the respective transponder in response to an electromagnetic signal emitted externally of the transponder. The identifying data corresponds to at least one of the respective one or more transponders and a respective product for tagging. The one or more transponders are attached to

respective ones of the products to tag the products with the corresponding identifying data.

Regarding dependent claim 11, it is submitted that because this claim depends from independent claim 1, which applicant believes is patentable over Reimels for the aforementioned reasons, it is submitted that present claim 11 is patentable for the same reasons.

Further, applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness. In particular, the Examiner has not pointed to any prior art reference that teaches or suggests the claimed combination of the two types of marking technologies, as called for by present claim 11. Instead, applicant submits that such combination is only found by hindsight reasoning and/or applicant's own disclosure. *See* MPEP 2142 *et seq.*

Accordingly, reconsideration of the rejection of claim 11 under 35 USC §103(a) as being unpatentable over Reimels in view of Ishikawa et al. is respectfully requested.

Claims 13 and 14 were rejected under 35 USC §103(a) as being unpatentable over Reimels as applied to claims 1-10 above, and further in view of *Uncommon Peril of Forgotten Surgical Tools*, Denise Grady, The New York Times, Jan. 21, 2003 (hereinafter "*Uncommon Peril*").

The Examiner acknowledges that Reimels does not disclose expressly the steps of x-raying a patient and removing a surgical sponge thereafter. However, the Examiner states that *Uncommon Peril* teaches that a patient suspected of

having a surgical sponge or other implement having a marker inside them can be x-rayed and if the implement is found to be there, it can be removed.

Applicant respectfully submits that present claims 13 and 14, as amended, patentably define over Reimels in view of *Uncommon Peril* – namely, because this combination of references does not disclose or suggest a method of detecting a surgical sponge within a surgical patient, said surgical sponge comprising three substantially spherical radiopaque markers, said markers being closely grouped to one another, each of said markers having an x-ray density equivalent to at least about 0.1 g/cm² of BaSO₄, said radiopaque markers being disposed in a relationship that is substantially fixed both in spacing and in orientation, and said method comprising the steps of: (a) obtaining at least one x-ray of at least a portion of said patient likely to contain said radiopaque markers; and (b) examining said x-ray to detect and locate an image of said sponge.

Accordingly, reconsideration of the rejection of claims 13 and 14 under 35 USC §103(a) as being unpatentable over Reimels in view of *Uncommon Peril* is respectfully requested.

Applicant's invention, as defined by present claims 1-7, 11 and 13-14 discloses a surgical sponge comprising three substantially spherical radiopaque markers, the markers being closely grouped to one another. Advantageously, this allows for a distinctive, visually recognizable shape in any direction when the sponge is exposed to an X-ray machine, since the imprint of the three closely grouped spheres is detectable in any direction.

The surgical sponge disclosed by present claims 1-7, 11 and 13-14 includes three closely grouped substantially spherical radiopaque markers – making their detection instantly recognizable, and does not even require the careful scrutiny of a trained radiologist to detect. This “signature” created by the grouping of three substantially spherical markers is an instantly recognizable indication that there is a retained sponge inside the patient. By way of comparison, the radiopaque strips taught by the prior art can easily be overlooked or even mistaken for something else because they do not consist of a unique shape or design. Therefore, unlike the prior art surgical sponges, applicant’s surgical sponge, as defined by present claims 1-7, 11 and 13-14 is readily detectable.

Applicant further submits that no additional searching by the Examiner is necessitated by the present amendments to claims 1-7, 11 and 13-14, because the limitations added to the independent claims of this application represent the very same limitations previously presented by claim 16, now cancelled.

CONCLUSION

In view of the amendments to the claims and the remarks set forth above, it is respectfully submitted that the present application is in allowable condition. Reconsideration of the final rejection, entry of this amendment and allowance of present claims 1-7, 11 and 13-14 are earnestly solicited.

Respectfully submitted,
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